

Lagerlöf & Leman
Final Draft
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To the Government and
the Ministry of Health and Social Affairs

APPEALS

APPELLANT

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IN RE

Warning texts for tobacco

DECISION AGAINST WHICH APPEAL IS MADE

Decision of the National Board of Health and Welfare on
January 9, 1991, ser. no. 344:1081/90

1. BACKGROUND

The National Board of Health and Welfare has stipulated new warning texts for tobacco products, Appendix 1. The National Board made a decision, among other things, about 16 new warning texts for cigarettes, 4 for so-called cartons, 12 for pipe and rolling tobacco and 6 for cigars/cigarillos. The decision entails very great changes of the rules concerning warning texts. Among other things, the system is expanded by the size of the warning text on cigarettes being increased threefold. Various pictorial elements and symbols are implemented along with every warning text and special longer warning texts are implemented on cartons of cigarettes in addition to the warning text on the packs of cigarettes.

2. PETITION

The appellant petitions that the Government

- 1) revoke the decision of the National Board of Health and Welfare
- 2) remit the matter to the National Board and

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3) declare that the warning texts shall follow the Warning Text Act and - as far as possible - follow the EC directive 1989/622.

If the National Board should feel that its decision is to be observed notwithstanding the appeal, a stop of execution of the same is petitioned.

3. GROUNDS

3.1 Introduction

3.1.1 The guidelines of the European Community

As early as 1988, the Government set down guidelines for Sweden's adaptation to the European Community (Sweden and Western European integration (Bill 1987/88:66). In directives (dir 1988:43) to committees and special inquiries, the Government has prescribed that the committees and special inquiries shall take into consideration the aspect of the EC in their inquiries and in their proposals to take advantage of possibilities that exist for harmonization. Then on 12 December 1990, the Swedish Parliament decided that Sweden shall apply for membership in the EC (report of the proceedings 90/91:44).

Therefore, today even stronger reasons exist for harmonizing the Swedish warning text system with the EC as far as possible. The Council of Ministers of the EC issued a directive in November 1989 (1989/622 EEC) to the member states referring to a harmonization of the rules concerning the marking of tobacco products, Appendix 2. On one large surface of the packet, the general warning, "Tobacco seriously damages health" shall be printed. In Addition, each EC member state shall draw up a list of warnings taken exclusively from those listed in the directive, and the specific warnings selected shall be printed on the two largest surfaces of each cigarette packet. The warnings shall cover 4% to 8% of each large surface of the cigarette packet depending upon the number of official languages. The reason the EC issued this directive is that the differences in the way the different countries regulated the marking of tobacco product was considered to constitute a trade barrier, and by doing so, being a threat to the free movement of goods within the EC. In the directive, it is expressly stated that this is the case (cf. page 1 of the directive), and furthermore the directive has been issued under Article 100a of the Treaty of Rome in order to reduce trade barriers. The intention is that the member states shall have adopted legislation that is in agreement with the directive at the latest by 31 December 1991.

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The directive states how packages of cigarettes shall be marked with warning texts and declaration of contents. Furthermore, the wording of the warning texts is given in the directive. The directive goes just as far as Swedish rules that are in force today in regards to warning texts and declaration of contents on tobacco products. It should be emphasized that the directive does not allow space for the member countries to implement different rules than that which the directive states even if stricter (cf. e.g. Art 8 and Art 4.2). The reason for this is that differences in marking are considered to constitute a serious trade barrier.

The decision by the National Board of Health and Welfare is in conflict with the EC directive in all respects (text, size, design, and format) and means that Sweden in a noticeable way departs from what applies in other EC countries. The decision is also diametrically opposed to the striving for adaptation that the Swedish authorities and Swedish legislation follow otherwise.

Attention must also be drawn to the rules of the EC in the light of the requirement of the law concerning warning texts that the warning texts shall be made as neutral as possible in regards to competition. Those who are affected by the new warning texts are, in the first place, the foreign producers who sell their products within the EC as well as in Sweden. These producers are forced to have very different kinds of packages for their products, one for sales within the EC and one for sales in Sweden. In addition to constituting a trade barrier, this increased cost would give rise to an unacceptable distortion of competition. Such cost increases hit products that have a small sales volume in such a way that the foreign companies will be forced to limit the selection of these products on the Swedish market. This forced restriction of assortment even conflicts with what is said in Bill 1975/76:49 p 13 about neutrality of competition.

3.1.2 The Warning Text Act

The decision of the National Board is even contrary to the law about warning texts and declaration of contents on tobacco products itself (1975:1154). According to the prefaces to the law about warning texts and declaration of contents on tobacco products (Bill 1975/76:49), the purpose of the legislation is to inform about possible health hazards that the use of tobacco entails. This is done by the packaging of the tobacco product being marked with a general warning text.

The purpose of the law is not, however, to restrict the possibilities of the businessman to market tobacco products.

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According to the bill, the warning text should be brief, easy to read and unambiguous. It may not be formulated as a generally held exhortation to refrain from the use of tobacco, but instead must be given a concrete content with information about what possible health hazards the use entails. It is to be a matter of factual information that builds upon results of research in the area (Bill 1975/76:49 p. 22). In the Bill, it is expressly stated that, for example, an altogether too generally held exhortation could be contrary to the regulations of the Freedom of the Press Act.

3.1.3 Freedom of the Press Act

All of the new warning texts of the National Board of Health and Welfare are in conflict with the Freedom of the Press Act.

According to the Freedom of the Press Act:

tobacco packages in their capacity as printed documents are included in the Freedom of the Press Act,

the Freedom of the Press Act does not permit an authority to decree that a printed document shall have a certain content without the support of the Freedom of the Press Act (ch 1 s 2 TF),

the regulations of the Freedom of the Press Act, in its capacity as constitutional law has priority to regulations in the law concerning warning texts and declaration of contents on tobacco products ("the Warning Text Act") to the extent that a conflict of law should arise,

and that formal support in the Freedom of the Press Act is missing for application of the Warning Text Act on printed documents, and that, therefore, there is no room for an extension of the warning text system.

Former Assoc. Prof. Hans-Gunnar Axberger (nowadays press agent ombudsman) has in an earlier appeal (Dnr M 709/85) in two opinions illuminated the conflict between the Warning Text Act and the Freedom of the Press Act. In a new opinion, 1990-02-27 (Appendix 3), Axberger has gone through the proposal that the consultative group of the National Board of Health and Welfare arrived at on 20 December 1990, and from which most of the warning texts are taken that can be found in the decision of the National Board. Axberger states in his most recent statement that room for that which can be prescribed in a warning text is very limited because of the regulations of the Freedom of the Press Act. Even pictorial elements containing meaning are included in the limitations.

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Axberger also sets forth the demand that the texts shall contain factual information based on research results. The demand for objectivity can be derived from a demand for neutrality in the presentation of the information the warning text is intended to convey. In other words, the demand for objectivity entails that the text shall not prescribe a behaviour but instead should inform about facts and allow the reader to make up his own mind. A "formation of public opinion" or putting forward views is not allowed to take place. The demand for objectivity must be fulfilled in order that the application of the Warning Text Act shall not be in conflict with the Freedom of the Press Act (Axberger 90-02-27 p 4 ff). Thus, from the point of view of freedom of the press the warning texts cannot be made larger than at present and neither can they contain a text or symbol that influences opinion.

The conclusions of Axberger concerning the implementation of larger squares for warning texts and pictorial elements, briefly, is that having warning text squares of such a size that the National Board has decided upon is a censuring interference in obvious conflict with the prohibition against censorship of the Freedom of the Press Act and that pictorial elements - to the extent that the pictorial elements contain meaning and influence views - presupposes that the requirement for objectivity and neutrality in presentation is fulfilled. (Axberger 90-02-27 pp 6 and 7).

The conclusions in Axberger's statement will be touched upon further down.

3.1.4 Trade mark legislation

The decision of the National Board is also in conflict with the Swedish law concerning trade marks and the so-called Convention of Paris. The Convention of Paris sets certain demands on the national laws of the member countries concerning protection of trade marks. In Article 7 and Article 6 *quinquies* (the so-called *telle quelle* rule) it is prescribed that the member countries cannot prohibit a businessman from registering and commercially using a trade mark or a packaging design. Foreign holders of trade marks have the right to register and use their trade marks in the form that they are registered in another country (*telle quelle*). Measures that intend to limit the use of the trade marks or the producers' possibility to decide, himself, the design of the package is in conflict with the Convention of Paris and the internal Swedish regulations concerning trade marks. Such measures, therefore, cannot be taken without special legislation.

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The property right to a trade mark further includes a right to freely use the trade mark. If a side of a package that is trade mark protected is taken up to a greater extent by a warning text - which the National Board has decided - then the design can no longer be regarded as a trade mark. The right to use the trade mark, which is the property of the holder, has in this way been violated. Such a violation could even be regarded as expropriation, and compensation, thus, shall be made according to ch 2 s 18 of the Instrument of Government Act, where protection of property is set down.

According to the decision by the National Board, for example, almost the entire side of one of the sides of a pack of cigarettes will be covered by a warning text and the consumers' identification of the pack, therefore, will be made more difficult and risk for confusion arises. This in turn means a distortion of competition. The risk is great that the consumers will be misled by the similar cigarette packs that will be the result of the distinguishing ability of the trade mark being strongly limited.

(The appellant intends to further submit complementing inquiries that deal with the warning texts being contrary to the laws concerning trade marks).

3.2 The decision of the National Board of Health and Welfare.

The National Board has made decisions about several changes in the warning text system in order to "strengthen the attention and reading value of the warning texts". The changes will be commented upon individually below under sections 3.2.1-3.2.3.

The reason for the changes that have been decided upon seems to be the assumption that the attention value of the texts has diminished. However, the National Board has not found any problems concerning the attention value of the warning texts. As far as is known, there is no investigation that shows that the attention value of the present warning text system has diminished. A basic requirement for a sweeping change in order to improve the attention value must be based on scientific investigations and facts. To carry out sweeping changes of the system on loose assumptions is in obvious conflict with the requirement that warning texts may only contain factual information based on results of research.

It should also be pointed out that the possibility of change in order to capture the attention of the public that is stated in the Warning Text Act refers to only the

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text itself. In the prefaces (Bill 1975/76:49 p 10) it thus says "in regard to the warning text, it can also be justified to vary it in order to capture the attention of the public".

As can be seen from sections 3.2.1-3.2.3., the appellant feels that the present warning text system should not be changed. If a change is to be made, then it must take place within the framework of the EC directive and in agreement with the Freedom of the Press Act, the Warning Text Act and other laws and conventions.

3.2.1. The increase in size of the square for the text

By the appealed decision, the National Board has stipulated that the size of the square for the warning text on a cigarette pack shall increase from the present 5 cm. x 2 cm. to 5 cm. x 6 cm. On packages that contain fewer than 20 cigarettes, cigars or cigarillos, however, the marking can be printed in diminished scale 4:5. The warning text on large packages (cartons) shall be 15 x 6 cm.

What the decision in this section means in practice can be seen in Appendix 4.

By way of introduction, it can be stated that the surface for the warning text has been increased threefold (10 sq. cm. / 30 sq. cm.). The statement by the National Board on p. 8 of the decision that the warning text takes up just more than a fifth of "the total surface of the package" is misleading. The National Board totally ignores that there are packages of different sizes on the market. The difference in size between the largest and the smallest is considerable. The statement of the National Board in its decision concerning the relation between the surface of the warning text and the total surface of the packaging lacks relevance since the decision prescribes that the warning text shall be placed on the outer side "that has the largest area".

A correct assessment of the surface that is taken up by the warning text should be based on a comparisons of the surface of the warning text in relation to the "largest area" on a normal-sized large and small packaging respectively. Such an assessment shows that the new squares for the warning texts will take up approx. 70%-80% of a normal-sized large package and even in certain cases run outside the package if the package is of a smaller size.

The decision to increase the size of the square for the warning text entails a considerable interference in the right of the producer to decide the design of the package. In principle, the decision entails that one of the sides is lost.

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In addition to this, the producers of smaller packages cannot even find space for the new warning texts on the pack. It will be impossible for the producer of, e.g. Commerce and More (packages of 20 cigarettes) to follow the new regulation since the warning text (5 cm. x 6 cm.) will be larger than the side "that has the largest surface". The package size for Commerce is 4.8 cm. x 6.9 cm. and for More the size is 4.6 cm. x 12.1 cm.), (cf. Appendix 5). Thus, the decision is so poorly thought out that as far as smaller cigarette packages are concerned, in many cases it cannot be followed.

As has been stated above, tobacco packages are, in their capacity as printed matter, protected in accordance with the Freedom of the Press Act. As it is put forward in the opinion, based on a strict interpretation of the Freedom of the Press Act, it is doubtful whether the Warning Text Act can be applied at all without agreement with the producers (Axberger 1990-02-27 p 1 ff). In order to arrive at such a possibility considerations must be made of legal policy and attention must be given to what the tobacco industry actually has accepted during a longer period of time. As is also apparent from the opinion, the scope for departure from the prohibition against censorship in the Freedom of the Press Act is very little. An expansion of the present system assumes, among other things, the acceptance of the tobacco industry. (Axberger 90-02-27 p. 6).

The increase in the size of the warning text that has been decided upon, therefore, is completely unacceptable regardless of the size of the package. The decree of the National Board that approx. 70%-80% of the largest surface of a normal-size package shall be taken up by the warning text is in obvious conflict with the prohibition against censorship in ch 1 s 2 TF. The space for the warning text that applies at present is more than adequate to satisfy the intention of the Warning Text Act.

Even more serious is that it is apparent from the proposal from the consultative group of the National Board of 1989-12-20, Appendix 6, page 5, that the intention of the consultative group with the increase in size is to "tighten the restriction of the producer's possibility to himself determine the design of the package". This shows that the National Board is consciously trying to violate legal rights of the tobacco industry in regards to freedom of the press and trade mark rights to convey commercial messages by way of their packages. On top of this, the National Board is well aware of the problem by way of a previous appeal and by comments of the tobacco industry on the proposal of the consultative group. Therefore, the new warning texts can be seen as a proposal to, so to say, by the back door, to implement a partial prohibition against use of one's package design on packages contrary to the Minister's statement in the prefaces to the law with certain

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regulations concerning the marketing of tobacco products (Bill 1977/78:178 p 29).

The increase of the size of the square for the warning text also runs into legal obstacles regarding trade mark rights. As was stated above, the Paris Convention prescribes that the member countries cannot prohibit businessmen from registering or commercially using trade marks or package design. Measures that are aimed at restricting the use of the producers' trade mark or package design are thus in conflict with the Paris Convention and the internal Swedish trade mark regulations.

The right to a trade mark includes, among other things, the right to use words and signs and protected package design on a product or a package.

The increased warning text surface even means there will be problems for the consumers. The decision means, in principle, that the appearance of the one side of the package is determined, i.e. a warning text. Different cigarette brands will therefore get a very similar appearance which will make consumer identification of the products more difficult.

It is apparent from what has been stated above that the decision to increase the size of the warning text conflicts both with constitutional law and general law. An increase in the size of the square of the warning text beyond that which applies at today can, therefore, not legally be carried out by the National Board.

The size of the new warnings are also in conflict with the EC directive.

3.2.2. The insertion of pictorial elements

As can be seen from the Freedom of the Press Act and the prefaces to the Warning Text Act (Bill 1975/76:49 p. 22), a warning text may only include factual information about health hazards that are based on the results of research in the area. From the requirement for objectivity, a requirement for neutrality can even be derived concerning the presentation of the information the warning text intends to convey (Axberger 90-02-27 p. 5). If a warning text goes beyond this, then it is in conflict with the Freedom of the Press Act.

From the point of view of freedom of the press whether a message is conveyed in words or pictures lacks importance. From this it follows that even the pictorial elements in the warning texts must fulfil the requirements for objectivity and neutrality in order not to be in conflict with the Freedom of the Press Act (Axberger 90-02-27 p. 7).

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The pictorial elements that have been decided upon are opinion-influencing. The pictures in, for example, warning texts 1, 3, 4, 6, 10, 11 and 15 can be regarded a pure scare-propaganda.

In none of the cases do the pictures fulfil the requirement for factual information about health hazards. The same round symbol is used by the National Board to illustrate cancer as to illustrate an ulcer (text no. 9) and asthma (texts no. 12 and 20). The pictorial elements are, therefore, misleading from a scientific point of view and can therefore not be considered a symbol as intended by the Warning Text Act. In addition, a number of the pictorial elements are extraordinarily difficult to decipher (texts 1, 2, 4, 10 and 15) and may be regarded as misleading even for this reason.

Most of the pictures are purely opinion-influencing and, in that respect, are not neutral. Warning texts with pictorial elements of the current kind are thus, in obvious conflict with the Freedom of the Press Act. Therefore, the warning texts shall not contain pictorial elements of this kind.

It is apparent from the prefaces to the Warning Text Act (Bill 1975/76:49) that the Norwegian warning text system is discussed. In Norway, warning texts occur together with one symbol. On page 22 in the prefaces, it is stated that "a symbol can be affixed in connection with the text". Thus, it may be assumed that the legislator has intended that a similar symbol that is used in Norway will be able to be used in Sweden. Such a symbol means an emblem or a sign that has a general meaning and which, therefore, is understood by people to be a symbol and not an illustration of the warning text. The Swedish warning texts that are now in force and the previous ones also contain, in a comparable way, only one symbol. On the other hand, it has never been the intention of the legislator to implement a number of different pictorial elements and symbols that illustrate each warning text. The pictorial elements that the Social Welfare Board has used in the new warnings are not symbols but rather drawings and illustrations of the warning texts. They do not have a general meaning and they are not abstract symbols. Therefore, the pictorial elements that the National Board has decided upon lack support in section 1 of the Warning Text Act and in the prefaces to the Act.

The pictorial elements shall therefore be removed from the warning texts as being in conflict with the Freedom of the Press Act as well as the Warning Text Act.

The pictorial elements are also in conflict with the EC directive.

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3.2.3 Special warning texts for cartons

3.2.3.1 Content of the texts

In the prefaces to the Warning Text Act, it is stated that the wording of the warning texts should be "brief, easy to read and unambiguous". Beyond these instructions regarding the wording itself of the texts, the warning text, as has been earlier stated, shall only contain factual information about health hazards based on research results put forward in a neutral manner.

The fine print in warning texts 17-20 (intended for cartons) is obviously not brief, easy to read and unambiguous. On page 3 of the decision of the National Board, the Board itself has stated that these texts are "longer". The newer, longer texts with "clarifications" and "commentaries" thus, lack support of the Warning Text Act.

What is more remarkable is that the content of texts 17 and 18, in addition, lies completely outside the scope "for factual information based on research that does not trespass on the area that is protected by freedom of the press" (Axberger 90-02-27 p. 8). As is apparent from Axberger's opinion, these texts are of a purely propagandistic nature, and they well-exemplify what an authority without support in the Freedom of the Press Act "never can force into printed documents" (Axberger 90-02-27 p. 8).

Texts 17-20 have completely lost the nature of ordinary warning texts, and thus should be excluded since they conflict with both the Freedom of the Press Act and the Warning Text Act.

Warning texts 19 and 20 are nearly an amalgamation of a number of earlier texts. Text no. 19 contains two different warning texts. It corresponds to text no. 5 with the addition of another warning: "New research results indicate that the risk of cancer of the kidneys and cervix is increasing".

Text no 20. contains four warnings. It both contains that part of one of the warning texts now in force ("Your smoking may harm others"), texts no. 12 and 14 and a new warning ("Long-term, passive smoking can increase the risk of lung cancer"). As the National Board's own legal secretariat pointed out in 1976 (Cf. the decision of the National Board, p. 8), the Swedish warning text does not allow more than one text per pack. Warning texts 19 and 20 contain a number of warning texts and, therefore, are in conflict with the Warning Text Act.

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3.2.3.2 Warning texts on both cartons and packs at the same time

In the prefaces to the Warning Text Act (Bill 76/76:49 p. 22) it is stipulated that marking, as rule, should take place on the "package in which the product normally is sold to the consumer. A special case is, for example, that a package contains a number of packs of cigarettes. In the same way, individually packed cigars occur in larger packages. The supervisory authority may, in such cases, determine which package or packages shall be marked".

It is apparent from this that the basic idea is that marking shall take place on the package that is normally sold. Most of the sales take place in the form of loose packs of cigarettes. Since consumption of cigarettes, without exception takes place from individual packs of cigarettes that contain warning texts, it is wrong to mark the cartons as well. This would mean that the same product would get two warning texts, which - as has been stated above - is not possible according to the Warning Text Act.

From the quotation above from the prefaces it is further apparent that the intention of the legislator has not been to allow the marking of cartons. It says, namely, in the prefaces that it is a "special case" that a package contains a number of packs of cigarettes. Cartons, however, have been in existence since at least well before the Second World War in Sweden, and if cartons were what was intended, then the legislator, in such case, would have said this expressly instead of talking about "special cases". What the legislator really intended was, probably the marking of some of the rare cigar and cigarette packs that contain small "inner packs". The intention of the legislator was that the National Board, in such cases, would be able to determine if the inner or the outer package would be marked.

Finally, it should be noted that warning texts on cartons of cigarettes is even in conflict with the EC directive, and thereby also in conflict with Parliament's striving for a European integration.

The decision about the marking of cartons with warning texts should, therefore, be revoked.

3.2.4 Incorrect handling of the matter

The National Board has referred the proposal of the consultative group of 1989-12-20 (See Appendix 6) to the tobacco industry for consideration. However, the decision of the National Board of 1991-01-09 contains both new and changed texts that were not referred earlier to the

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tobacco industry for consideration. All of the pictorial elements in the warning texts are also new and have not been previously seen by the tobacco industry.

It is apparent from the prefaces of the Warning Text Act (Bill 1975/76:49 p. 22) that the National Board of Health and Welfare is to obtain the views of the tobacco industry. This has only taken place concerning certain texts and not in any case concerning pictorial elements.

The action of the National Board is surprising considering that the National Board well knows from an earlier appeal that the parties concerned shall be offered the opportunity to express their opinions about new warning texts, and that the tobacco industry has asked the National Board to be able to examine possible symbols and changed warning texts. The appellant wishes, therefore, that the Government stress anew for the National Board the importance of following the legal procedure and providing the tobacco industry with the opportunity of expressing its opinion about all of the warning texts before a decision is reached.

3.3 The warning texts - the individual texts

The scientific literature chosen by the Social Welfare Board as scientific references for the new warning texts is selective and omits references to studies and papers demonstrating a different opinion. In spite of the requirement of the Warning Text Act to have factual information based on scientific studies, many of the new warning texts seem to rely on scare tactics. The appellant cannot, in any respects, agree to any of the warning texts that the National Board has decided on. In the following, however, the presentation is limited to those warning texts the wording of which is directly in conflict with the Freedom of the Press Act, the Warning Text Act and other legislation.

Text No. 3 - "Tobacco smoke contains arsenic, lead, cadmium and many other harmful substances"

The text is directly misleading since it gives the impression that arsenic, lead and cadmium occur in harmful amounts in tobacco smoke. Although tobacco smoke constituents may be among the most heavily researched substances in the world, no constituent at the levels found in cigarette smoke, has been scientifically proven to cause cancer or any human disease. Arsenic, lead and cadmium are so-called trace elements that exist almost everywhere in nature, in the same amounts or larger amounts than that which occurs in tobacco smoke. All of these substances are found in ordinary foodstuffs such as potatoes, different kinds of cereal, spinach, fish and shellfish. In tobacco smoke these trace elements are found in such small amounts that they are well below what the National Food Administration accepts as admissible

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for foodstuffs. It is, therefore, misleading to try to insinuate that these trace elements in tobacco smoke are harmful.

In addition to this, the pictorial element portrays tobacco smoke as a deadly poison by using the symbol of a skull. This is grossly misleading with regard to the fact that the trace elements in tobacco smoke that are mentioned fall below what the National Food Administration accepts as admissible for foodstuffs. The skull is also a so-called "danger symbol" that may only be used when marking lethal and very dangerous poisons, according to the instructions of the Chemical Inspection Board. The pictorial element is, therefore, misleading for the consumers. The requirement for objectivity is, thus, not fulfilled; for which reason the text and the pictorial element comes into conflict with the Freedom of the Press Act and the Warning Text Act.

Text No. 4 - "A heart attack before 50 strikes almost only smokers"

From a scientific point of view the risk-factor analysis in the paper cited by the Social Welfare Board as scientific reference, is highly doubtful. Confounding factors such as, for example, stress, social factors, personality type, physical exercise etc. are virtually not considered. If you are under fifty and not a smoker there is, however, still a risk of heart attack. The warning text is, therefore, misleading because it distracts the attention from the many other risk factors for heart diseases that exist, and it gives the impression that if you do not smoke and if you are under fifty you will not have a heart attack.

The Social Welfare Board gives a false assurance to people under fifty who are non-smokers or smokers who are willing to quit smoking not to consider the other risk factors in their lives. The warning text, therefore, seems to counteract the Social Welfare Board's own goal to inform society about all kinds of health risks in a scientific and balanced manner.

Text No. 7 - "Many smokers who have a perpetual morning cough think that this is normal. It isn't. Most often it is due to smoking."

The National Board refers to older literature from 1979 at the same time as the Board justifies the new warning text by saying that today we "have considerably greater knowledge about....the health hazards of tobacco". (Page 1 of the decision). If this is a new health hazard that justifies a new warning text, then new literature should be cited. As far as we are aware, no such literature exists. The text and the pictorial element are in conflict with the requirement that the warning text shall be unambiguous and only contain factual information about health hazards. The pictorial element seems to show

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somebody in pyjamas coughing. It cannot be considered as a symbol for anything, but is rather an illustration which does not fulfil the requirement of the Warning Text Act.

Text No. 10 - "Smoking contributes to the skeleton becoming more fragile. Older women are especially vulnerable".

This text is not based on scientific facts. The most recent report of the Surgeon General (U. S. Surgeon General, 1990; cf. page 453) summarizes the situation today in regard to scientific research as follows: "There is insufficient evidence to conclude that smoking decreases bone mineral content and the risk of osteoporotic fractures".

The pictorial element is intended to scare and influence women's views about smoking by creating the impression that arms and legs can fall off if women smoke. The pictorial element is, therefore, even in conflict with the Freedom of the Press Act.

Text No. 11 - "Both smoking and using moist snuff increases the risk of cancer of the mouth. Smoking also contributes to loosening of the teeth".

The warning text gives the impression that smoking increases the risk of loosening of the teeth.

It is difficult to find support for the opinion of the National Board of Health and Welfare in the literature that is cited by the Board. Instead, there are a number of publications available that come to a completely different conclusion than that of the National Board.

The Swedish researchers, Bergström and Floderus-Myrhed conclude from their experiments with twins in this matter that it is apparent that the change for the worse in the health of the smoker with regard to inflammation of the gums and loosening of the teeth was "on the borderline of statistical significance" and "the result of gingival bleeding is contrary to expectation. Out of 63 pairs with different bleeding propensity the high exposed twin showed more impaired status in only 20 cases. This means that in 43 cases the low exposed twin had more impaired status. The probability of this outcome having occurred by chance is less than 0.01".

The warning text is not based on the results of research in the area.

The pictorial element is some kind of scare propaganda that intends to show that a number of teeth drop out of the mouth of the person who smokes. Therefore, the pictorial element is even in conflict with the Freedom of the Press Act.

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Text No. 12 - "Most people with asthma have hyper-sensitive bronchial tubes. Your tobacco smoke can aggravate the complaint."

The warning text is not based on adequate scientific information. Clinical studies on asthmatics do not conclusively support the claim in the text. While two studies are suggestive of a response to ETS, four studies report no objective changes in asthmatics even after prolonged, heavy exposure to ETS. Also, in the two studies reporting an effect from ETS exposures among asthmatics, researchers were unable to rule out the influence of emotional and psychological stress on the reactions of their patients.

Asthma is a hypersensitive condition, which can be aggravated by all types of air pollution. The most common problems are dust, mites, mold, pets, birds, fungus and bacteria.

Text No. 13 - "Children who are exposed to tobacco smoke more often suffer allergic complaints."

There have been claims that individuals are allergic to tobacco smoke. Some individuals claim to be annoyed or irritated simply by the sight or smell of ETS, but scientific research reveals that there is no tobacco smoke allergy per se, in that specific allergens have not been identified in tobacco smoke. Thus, while some individuals for whatever reason may react to ETS exposures, such responses are not specific sensitizations to tobacco smoke. A recent investigation, for example, reports that exposure to ETS does not increase sensitization to common allergies in children. (Ownby, 1988). The warning text is, therefore, not based on sufficient scientific information.

Text No. 14 - "Do the children often have coughs? Children who are exposed to tobacco smoke more often suffer serious infections of the respiratory passages".

None of the studies which claim such an association have actually measured exposure to ETS and virtually all of the studies fail to control for cross-infections in the home, attendance at day care centers (and subsequent transmission of viral infections) or genetic susceptibility to childhood respiratory illness. Studies which control for such factors report no significant increased risk of infections among children of smoking parents.

If children often cough, then one should see a doctor in the first place. The text gives a misleading impression that it would be enough not to smoke in the vicinity of children. This can have the serious effect that coughing children do not get the medical care they need. The warning text is not based on adequate scientific

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information and the requirement for objectivity is not fulfilled.

Text No. 15 - "Smoking creates addiction. Nicotine causes a physical addiction in a similar way as heroin or cocaine"

This comparison to heroin and cocaine is utterly misleading and is counteracting the Social Welfare Board's own goal to reduce drug abuse in Sweden. The use of heroin and cocaine is connected with a destruction of the personality and with serious criminality. These drugs destroy people and society. Everybody knows that smoking does not cause these kinds of effects.

The text, therefore, trivializes in a flagrant way the serious threat that narcotics constitutes in today's society. The text can, especially among young people, be understood in the reverse, i.e. so that using heroin and cocaine is not a greater risk than smoking. And furthermore that it is just as easy to quit heroin and cocaine as it is to quit smoking.

The scientific definition of addiction generally includes objective physiological effects of drugs - namely intoxication, physical dependence, withdrawal and tolerance. These effects are seen in heroin and cocaine addicts but not in cigarette smokers. Some recent definitions of addiction are so broad that they can apply to almost any strong habit. Watching television, exercising, and even shopping and playing video games have been called addictions. Broad definitions of addiction are meaningless because they include such a wide variety of activities. Because true drug addicts are usually either intoxicated or experiencing physical withdrawal, they are unable to make rational decisions concerning their lives in general, much less specifically whether to continue or quit drug use. By contrast, smokers are always able to think rationally. Smokers can, thus, decide to quit or continue to smoke.

The statement in the proposed warning text regarding heroin and cocaine is based on a claim made in the 1988 U. S. Surgeon General's Report. The statement, however, has been strongly criticized by scientists and clinicians from a number of countries.

The National Board, itself, in a proposal for an earlier warning text that the government subsequently rejected, has pointed out that it is easy to quit smoking: "Do you want to quit smoking? Many people have done this. Decide upon a certain day and quit right away". It is further apparent from the information that has been made available by the Surgeon General in the U. S. that 41 million people quit smoking in the U. S. (Surgeon General, 1988) and NTF and VISIR in Sweden that tens of thousands of smokers quit smoking yearly. Nearly half of

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all living adults who ever smoked have quit according to the U. S. Surgeon General (Surgeon General, 1989).

The pictorial element tries to portray smokers as "high" narcotics addicts with wide-open eyes and very enlarged pupils. The pictorial element gives a completely misleading picture of smokers. By its way of influencing opinion, the pictorial element is even in conflict with the Freedom of the Press Act.

The text and the pictorial element are, moreover, frightening and agitating. The requirement for factual information based on scientific results, objectivity and neutrality has been totally ignored by the Social Welfare Board.

Texts Nos 17 and 18

- "Stefan started smoking as early as when he was in junior high school. By the age of twenty, he was smoking a pack a day. Twenty years later, he was still perfectly healthy, even if he was out of shape. But one afternoon, he suddenly collapsed at work. Before the end of the day he was dead. Cause of death: heart attack. He was 40 years old.

Smoking causes a five to ten times greater risk of dying of a sudden heart attack in one's younger years".

"Karin started to smoke when she was eighteen. She smoked almost a pack a day. She tried to quit many times, but that was difficult since many of her friends at work smoked. Just prior to her 37th birthday, she started to cough more than usual and started losing weight. Karin went to a doctor who discovered a discoloration on the lung when it was x-rayed. Further examination revealed a type of lung cancer that almost exclusively afflicts smokers and which is very difficult to cure. Half a year later, Karin was dead.

The number of women who die of lung cancer is increasing dramatically. This is due to smoking."

It is clear that the texts are in conflict with the requirement of the Warning Text Act for brief, easy to read and unambiguous texts. It even conflicts with the requirement for factual information based on research.

It is important that the Social Welfare Board gives correct figures in the warning text instead of trying to terrify smokers. In text no 17, the risk factor of 5 to 10 times is wrong because no scientific study shows such high risk factors.

The texts constitute a considerable departure from what applies today. No other country has texts like these. The texts are almost like moral stories and anecdotes without

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the nature of a warning text. From a scientific viewpoint it is also important to underline that you cannot take anecdotal stories and generalize them into a warning text.

Text No. 18 is, furthermore, according to the Social Welfare Board a combination of two cases, which is further misleading to the consumer who, of course, will believe the stories about Karin and Stefan.

The Social Welfare Board itself has stated that it has based the warning texts on real cases, in which however, facts had been changed in important respects. The warning texts give the impression of being true stories about people named Stefan and Karin who existed. This is not the case, and the texts do not fulfil the requirement for factual information. In addition, it can be said that very few cases exist where a 37 year old woman has got lung cancer. The text is, therefore, not representative, and you cannot conclude the final sentence which contains a warning from the story about Karin.

Regarding warning No. 17, there are not enough details about "Stefan" to venture many hypotheses about what factors might be responsible for his heart attack. Focusing on a single facet of an individual's life, to the total exclusion of all other potentially relevant factors, is misleading and it grossly oversimplifies the numerous complex mechanisms underlying heart disease. The warning does describe "Stefan" as "out of shape." Does that mean that he had become overweight, or even obese? Does this mean that he did not engage in regular exercise? Does this reflect a general personality trait of someone who did not take care of himself? Does this mean that he had a hurried, stressed lifestyle that left him with little time for exercise or proper eating? Does this indicate that in general he had poor nutritional habits and ate foods high in fat or sugar?

Being "out-of-shape" could mean any or all of these things. The narrative about "Stefan" also suggests that his heart attack occurred on a work day. Many factors associated with the work environment have been reported to be statistically associated with heart disease. These include such factors as job satisfaction, the authority structure, the nature of the tasks, the level of stress and latitude in decision-making. It is not possible to generalize from a case like that described in No. 17. Therefore, the warning is not factual information.

The scientific relevance in the stories is completely missing, and the texts no longer have the nature of being warning texts.

Text No. 20 - "Your smoking can harm others!"

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- Children who are exposed to tobacco smoke more often suffer serious infections of the respiratory passages.
- Many people suffer from allergies and other hypersensitivity. The tobacco smoke of others can aggravate the complaint.
- Long-term passive smoking can increase the risk of lung cancer.

The appellant's comments regarding the proposed texts 12, 13 and 14 also apply to this text, all but the last sentence of this warning text.

There is no scientifically proved causal connection between "passive smoking" and lung cancer, and in any case there is no scientific consensus in the question. Smoking is just one of many factors regarding indoor air quality. The overwhelming majority of the scientific studies in the world regarding ETS and lung cancer have not reported a statistically significant increase in lung cancer in non-smokers (21 out of 26 studies). The requirement for scientific information based on research is, because of that, not fulfilled. In addition, the text conflicts with the requirement of the Warning Text Act for brief and easy to read texts.

4. SUPPLEMENT

The appellant reserves the right to further supplement the grounds and arguments of this appeal.

5. CONCLUSION

We have demonstrated that the Social Welfare Board has decided to radically expand the warning text system in a manner that conflicts sharply with Swedish constitutional law and the Act on HWL. The decision also means that the National Board of Health and Welfare violates the right of the appellant to design his packages that are protected by the freedom of the press and the right to use his trade mark. Therefore, the decision is an encroachment on both the personal and economic conditions of the appellant. Furthermore, we argue that the decision even conflicts with the EC directive and with the Sweden's striving towards adaptation to the EC.

The appellant would recommend that, instead, Sweden move closer to the EC and introduce a series of tobacco health warnings that follow the scheme laid out in the EC Directive 89/622, while complying at the same time with Swedish constitutional and general legislation. The essence and substance of the present and proposed Swedish warnings would be met by a selection from the EC list of warnings. In this way, Sweden should attain harmonization with the EC in the area of tobacco trade and production.

On this positive note, we again respectfully request you to send the decision back to the National Board of Health

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and Welfare with instructions that new warning texts shall be in agreement with the EC directive.

Stockholm

January 30, 1991

Allan Stenshamn

Peder Hammarskiöld

Appendices:

Certificate of registration
Power of attorney

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